

Cadence Pharmaceuticals Reports Positive Outcome In OFIRMEV® Patent Litigation

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SAN DIEGO, Nov. 14, 2013 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (NASDAQ: CADX), a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, announced today that the U.S. District Court for the District of Delaware has ruled in favor of Cadence in the company's patent infringement lawsuit against Exela Pharma Sciences, LLC.

"We are very pleased with the Court's decision, as it confirms our belief in the strength and validity of the patents covering OFIRMEV," said Ted Schroeder, president and chief executive officer of Cadence. "Our focus remains on continuing to drive OFIRMEV's strong performance. We continue to gain market share and posted year-over-year sales growth of more than 100% in each quarter of 2013. We remain confident in our franchise, and look forward to updating investors further on our progress."

In August 2011, Cadence and SCR Pharmatop, the patent owner, filed suit against Exela for infringement of two patents covering OFIRMEV® (Acetaminophen) Injection, U.S. 6,028,222, which expires on August 5, 2017 (or February 5, 2018, if pediatric exclusivity is granted), and U.S. 6,992,218, which expires on June 6, 2021 (or December 6, 2021, if pediatric exclusivity is granted). The Court rejected Exela's claims that these patents are invalid and found that Exela's ANDA for a generic version of the product infringes both of these patents.

About OFIRMEV® (Acetaminophen) Injection

OFIRMEV (acetaminophen) injection (1000 mg / 100 mL, 10 mg / mL; for intravenous use only), Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen, is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. The FDA approval of OFIRMEV was based on data from clinical trials in approximately 1,020 adult and 355 pediatric patients. These trials included two studies evaluating the safety and effectiveness of OFIRMEV in the treatment of pain, and one study evaluating OFIRMEV in the treatment of fever. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age.

Important Safety Information

RISK OF MEDICATION ERRORS AND HEPATOTOXICITY

Take care when prescribing, preparing, and administering OFIRMEV injection to avoid dosing errors which could result in accidental overdose and death.

OFIRMEV contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment. Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur, or at the first appearance of skin rash. Do not use in patients with acetaminophen allergy.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. The antipyretic effects of OFIRMEV may mask fever in patients treated with postsurgical pain. OFIRMEV is approved for use in patients ≥ 2 years of age. Do not exceed the recommended maximum daily dose of OFIRMEV. OFIRMEV should be

administered only as a 15-minute infusion.

For more information, please see the full OFIRMEV Prescribing Information, including the complete boxed warning, which is available at www.OFIRMEV.com or www.cadencepharm.com.

About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. The current version of Cadence Pharmaceuticals' corporate overview may be viewed on the Investors page of www.cadencepharm.com under "Events & Presentations" by selecting "Corporate Overview."

Forward-Looking Statements

Statements included in this press release and Cadence's conference call that are not a description of historical facts are forward-looking statements. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements, and are based on Cadence's current beliefs and expectations. Such statements include, without limitation, statements regarding: Cadence's belief that OFIRMEV is continuing to gain market share; the company's ongoing intellectual property litigation and related expenses; and the company's guidance regarding anticipated net product revenue from sales of OFIRMEV for the twelve months ending December 31, 2013. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cadence's actual future results may differ materially from Cadence's current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence's dependence on the successful commercialization of OFIRMEV, which is the company's only product; Cadence's ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; Cadence's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of OFIRMEV to meet market demand; Cadence's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including in current intellectual property litigation with the parties that have submitted new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that Cadence may be required to continue intellectual property litigation for substantial lengths of time or file additional lawsuits to defend its patent rights from challenges by companies that have submitted NDAs or ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential introduction of generic competition to OFIRMEV in the event Cadence is unsuccessful in current or future intellectual property litigation, and the impact it may have on the sales and pricing of the product; Cadence's dependence on its licensors for the maintenance and enforcement of its intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products Cadence may in-license or acquire; Cadence's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; public concern regarding the safety of drug products such as OFIRMEV, and the potential implementation by regulatory agencies of new requirements to include unfavorable information in the labeling for OFIRMEV; the risk that Cadence may not be able to raise sufficient capital when needed, or at all; and other risks detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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